

REMARKS

This Amendment is responsive to the final Office Action dated October 4, 2010.

Applicant has amended claims 1, 6, 11, 17, 18, and 35.

Applicant has amended independent claims 1 and 35 to positively recite that the plurality of stimulation electrodes defines a plurality of stimulation vectors. This amendment is consistent with that suggested by the Examiner in the final Office Action, and does not present any new issue that would require further searching as the Examiner previously examined the claims with this feature inferentially included.¹ As such, Applicant requests entry of the amendment to independent claims 1 and 35.

Upon entry of this Amendment, claims 1–9, 11–18, 20–31, and 33–38 will be pending.

Allowable Subject Matter

In the final Office Action, the Examiner objected to claims 20–26, 37, and 38 as including subject matter that would be allowable if rewritten in independent form.

Applicant notes that claim 37 was presented in independent form, rather than dependent form, in Applicant's previous Amendment dated November 18, 2009. Further, claims 20–26 depend from claim 37, either directly or indirectly. Consequently, Applicant submits that the Examiner erroneously objected to claims 20–26 and 37 in the final Office Action, and these claims should have been indicated in the final Office Action as allowable. Applicant requests withdrawal of the objection and allowance of these claims.

With respect to claim 38, Applicant thanks the Examiner for the indication of allowability, but declines to amend claim 38 into independent form at this time.

Information Disclosure Statement

As discussed in the Amendment filed on November 18, 2009, the Examiner did not consider all references listed in the 1449 form that accompanied the Information Disclosure Statement filed on July 21, 2009. In particular, Applicant notes that the Supplemental European Search Report dated May 8, 2009 for corresponding European Patent Application 01973465.6-1265 was lined through in the copy of the 1449 form supplied by the Examiner. Applicant

¹ Final Office Action dated Oct. 4, 2010, Item 3. Applicant notes that MPEP 714.13(II) indicates that an amendment that adopts an examiner's suggestion does not require that a showing under 37 CFR 1.116(b)(3) for entry after final rejection.

respectfully requests that the Examiner consider all references listed in the Information Disclosure Statement and provide an initialed copy of the 1449 form indicating that all references have been considered along with the next official action, or provide an explanation as to the reason the Examiner is not considering the Supplemental European Search Report.

The Examiner failed to address Applicant's remarks made in Applicant's previous submission regarding the Supplemental European Search Report. Applicant respectfully requests clarification regarding the Examiner's failure to consider the Supplemental European Search Report.

Claim Objections

In the final Office Action, the Examiner objected to claims 1, 5, 6, 11, and 18 because of several alleged formalities. With respect to claim 1, the Examiner stated "[c]laim 1 is objected to as no element has been set forth to create/generate the stimulation that is delivered."² Applicant respectfully submits that Applicant is not required to positively set forth an element to create or generate the stimulation. The Examiner failed to cite to any portion of the MPEP or other authority as a basis for requiring Applicant to set forth an element to create or generate the stimulation in claim 1. Applicant notes that claim 1 includes the feature of an implantable gastric stimulator that delivers electrical stimulation when the sensed intrinsic gastric activity is classified as normal.

With respect to claim 5, the Examiner stated "[c]laim 5 is objected to as the claim states that the stimulator is a microprocessor; it is unclear how a microprocessor performs the functions of a stimulator."³ Applicant respectfully disagrees that claim 5 "states that the stimulator is a microprocessor." Instead, claim 5 recites that the implantable gastric stimulator comprises a programmable microprocessor or microcontroller. As described in Applicant's originally-filed disclosure, the implantable gastric stimulator may be a small, compact pulse generator that internally contains electronic circuitry and a power supply.⁴ The electronic circuitry may include a microprocessor, electrical sensing circuitry, electrical stimulation circuitry, telemetry circuitry, and random access memory.⁵ Thus, in some examples, consistent with claim 5, the

² Final Office Action dated October 4, 2010 at p. 2, item 4.

³ *Id.* at p. 2, item 5.

⁴ See Applicant's originally-filed disclosure at p. 12, ll. 6-9.

⁵ *Id.* at p. 12, ll. 11-15.

microprocessor may be a component of the implantable gastric stimulator. Applicant requests withdrawal of the objection.

With respect to claims 6 and 11, the Examiner stated “[c]laims 6 and 11 recite the word ‘may’. This is vague as it does not state that the claim actually has to include the limitations.”⁶ Applicant has amended claims 6 and 11 to delete the word “may.” In view of the amendment to claims 6 and 11 presented above, Applicant submits the objection to claims 6 and 11 is rendered moot. Withdrawal of the objection is requested.

With respect to claim 18, the Examiner stated “[c]laim 18 is objected to as reciting the following limitation, ‘a temporal offset.’ This is vague as it is unclear what temporal offset is offset from.”⁷ Applicant has amended claim 18 to depend from claim 16 instead of from claim 13. In view of the amendment to claim 18 presented above, Applicant submits the objection to claim 18 is rendered moot. Withdrawal of the rejection is requested.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1–9, 11–18, 27, 28, and 35 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner stated:

Claim 1 recites the limitation “a plurality of stimulation vectors” in lines 15-16. There is insufficient antecedent basis for these limitations in the claim. These terms are inferentially included. It is unclear if the applicant is positively reciting the elements. It is suggested to first set forth that the plurality of stimulation electrodes provide a plurality of different stimulation vectors. It is noted that support will be needed to be pointed out in the originally filed written description.⁸

Although Applicant does not acquiesce in the Examiner’s rejection of claims 1–9, 11–18, 27, 28, and 35 under 35 U.S.C. § 112, second paragraph, Applicant has amended independent claims 1 and 35 in order to advance prosecution of the application. In particular, Applicant has amended claims 1 and 35 to clarify that the plurality of stimulation electrodes defines the plurality of stimulation vectors. Support for the amendment to claims 1 and 35 can be found

⁶ Final Office Action dated October 4, 2010 at p. 2, item 6.

⁷ *Id.* at p. 3, item 7.

⁸ *Id.* at p. 2, item 3.

throughout Applicant's originally-filed disclosure, such as in FIGS. 6 and 7 and at page 13, lines 15-24 and page 16, lines 18-21.

Applicant submits that claims 1-9, 11-18, 27, 28, and 35, particularly as amended, satisfy the requirements of 35 U.S.C. § 112, second paragraph. Consequently, Applicant respectfully requests withdrawal of the rejection of claims 1-9, 11-18, 27, 28, and 35 under 35 U.S.C. § 112, second paragraph.

Claim Rejection Under 35 U.S.C. § 103

In the final Office Action, the Examiner rejected claims 1-9, 11-18, 27-31, and 34-36 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cigaina (U.S. Patent No. 5,423,872) in view of Douglas (U.S. Patent No. 5,292,344) and Gordon et al. (U.S. Patent No. 6,684,104; hereinafter "Gordon").

Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest each and every feature of Applicant's claims, and there would have been no apparent reason for modification to include such features.

Independent Claims

Independent claim 1 as amended is directed to a system for gastric stimulation of a patient that includes a plurality of sensing electrodes for sensing intrinsic gastric activity from a stomach wall of a patient, an implantable gastric stimulator coupled to the plurality of sensing electrodes, the implantable gastric stimulator configured to receive the sensed intrinsic gastric activity and perform an analysis of the sensed intrinsic gastric activity to classify the activity as normal or abnormal, and determine whether to create an electrical stimulation based at least in part upon the classification of the sensed intrinsic gastric activity as normal or abnormal, where the implantable gastric stimulator delivers the electrical stimulation when the sensed intrinsic gastric activity is classified as normal, a plurality of stimulation electrodes configured to convey the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient, where the plurality of stimulation electrodes defines a plurality of stimulation vectors and where the electrical stimulation is configured to disrupt normal gastric activity of the stomach and the implantable gastric stimulator is configured to switch between any of the

plurality of stimulation vectors depending upon the sensed intrinsic gastric activity. Cigaina in view of Douglas and Gordon fails to disclose or suggest the features of claim 1.

In the final Office Action, the Examiner stated:

Cigaina discloses a gastric pacemaker that senses particular electric activity and then provides “on demand” stimulation (Col. 3, ll. 41-45). Cigaina further discloses that the system stimulates to disrupt normal slow waves and prevent emptying of the stomach ... Cigaina discloses a system that senses and then disrupts normal activity, it is silent as to if the gastric pacemaker includes multiple electrodes.⁹

The Examiner also included this statement in the nonfinal Office Action dated August 18, 2009. In the Applicant’s Amendment filed on November 18, 2009, Applicant submitted remarks detailing the Examiner’s mischaracterization of Cigaina. However, the Examiner failed to address Applicant’s remarks in the final Office Action.

In particular, as discussed in the Amendment filed on November 18, 2009, Applicant disagrees with the Examiner’s assertion that Cigaina discloses or suggests classification of sensed intrinsic gastric activity as normal or abnormal. Contrary to the Examiner’s assertion, Cigaina does not suggest the classification of sensed intrinsic gastric activity as normal or abnormal. In a portion of Cigaina cited by the Examiner, Cigaina generally states that “[t]he stimulator can be programmed for both continuous stimulation and for ‘on demand’ stimulation, i.e., at the onset of a particular electrical activity which can be detected by the stimulator itself through the electrocatheter.”¹⁰

Although Cigaina appears to describe delivering electrical stimulation to alter the natural gastric motility upon the onset of a particular detected electrical activity, Cigaina fails to disclose or suggest in any manner that the stimulator analyzes the sensed intrinsic gastric activity to classify the activity as normal or abnormal. For example, Cigaina fails to describe any particular type of activity that triggers the on-demand stimulation, much less specify that normal intrinsic gastric activity triggers the on-demand stimulation. Cigaina also fails to disclose or suggest that the sensed electrical activity is unique to any particular type of stimulation delivered to the patient. Further, Cigaina fails to disclose or suggest that any type or amount of analysis or classification occurs upon detecting this unidentified electrical activity. Accordingly, contrary to

⁹ *Id.* at p. 3, items 11 and 12.

¹⁰ Cigaina, col. 3, lines 41-45.

the features of independent claim 1, Cigaina is devoid of any suggestion that the stimulator analyzes the sensed intrinsic gastric activity to classify the activity as normal or abnormal.

Neither Douglas nor Gordon overcomes this deficiency. For at least these reasons, the cited art fails to disclose or suggest each and every feature of independent claim 1, and the Examiner failed to establish a *prima facie* case for non-patentability of claim 1 under 35 U.S.C. § 103(a).

In addition to the above deficiency, the cited references also fail to disclose the feature of an implantable gastric stimulator that is configured to switch between any of a plurality of stimulation vectors depending upon sensed intrinsic gastric activity. In the final Office Action, the Examiner stated:

Cigaina in view of Douglas discloses the claimed invention but fails to teach that the system can switch between any of a plurality of vectors. However, Gordon teaches that it is known to use a gastric stimulator with multiple electrodes that can [be] implanted in a large patch and then is capable of switching between the various electrodes to form vectors that stimulate the best based on sensed activity as taught in (e.g. Col. 16, ll. 16-40; Col. 20, ll. 25-46) to provide the physician with the time saving task of installing individual electrodes, thereby reducing the time required for electrode installation.¹¹

Applicant respectfully disagrees with the Examiner's characterization of Gordon. Gordon fails to disclose or suggest an implantable gastric stimulator that is configured to switch between any of a plurality of stimulation vectors depending upon sensed intrinsic gastric activity, as required by claim 1.

Gordon is directed to an apparatus for stimulating neuromuscular tissue of the gastrointestinal tract and methods for installing the apparatus to the neuromuscular tissue.¹² In a portion of Gordon cited by the Examiner, Gordon discusses a patch 324 which supports electrodes 315, 317, 319, and 321, as illustrated in FIGS. 17, 18, and 19 of Gordon.¹³ (FIG. 17 of Gordon is reproduced below for purposes of illustration.) Gordon discloses that the electrodes may be distributed around the distal surface 326 of the patch 324 substantially equidistantly from the center of the distal surface 326.¹⁴ Gordon further discloses that, if an array of electrodes is being used for multiple stimulation vectors, [an] eccentric placement of the electrodes may be

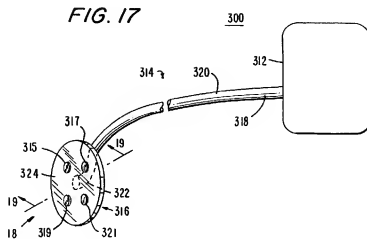
¹¹ Final Office Action dated October 4, 2010 at p. 4.

¹² See Gordon at Abstract.

¹³ *Id.* at col. 15, ll. 43-45.

¹⁴ *Id.* at col. 16, ll. 27-29.

preferred to phase the stimulating pulses and, consequently, the contractions induced by the stimulating pulses.¹⁵



In another portion of Gordon cited by the Examiner, Gordon discusses electrode switching circuitry that enables a pair of electrodes to be used for sensing, and a pair or pairs of electrodes to be used for stimulation.¹⁶ Gordon additionally discloses that the stimulation and sensing may utilize the same electrodes and that, during the stimulation period, the electrode switching circuitry can change the polarity of the stimulation electrodes to create multi-phasic pulses, alternating polarity between pulses or a series of pulses and different stimulation vectors.¹⁷ Gordon further discloses that the switching circuitry can also enable different pairs of sensing electrodes to sample gastric electrical activity at various sensing locations or along different vectors.¹⁸

Although the two cited portions of Gordon generally refer to stimulation vectors, Gordon simply describes that electrode switching circuitry can change the polarity of different stimulation vectors and separately enable different pairs of sensing electrodes to sample gastric electrical activity along different vectors. Nowhere does Gordon disclose or suggest switching between any of a plurality of stimulation vectors depending upon sensed intrinsic gastric activity, as required by claim 1. Indeed, at no point in the portions of Gordon cited by the Examiner does Gordon describe switching between a plurality of stimulation vectors based on any sensed

¹⁵ *Id.* at col. 16, ll. 29–33.

¹⁶ *Id.* at col. 20, ll. 29–31.

¹⁷ *Id.* at col. 20, ll. 32–36.

¹⁸ *Id.* at col. 20, ll. 37–39.

activity, much less switching between any of a plurality of stimulation vectors depending on sensed intrinsic gastric activity.

Consequently, even if Cigaina in view of Douglas was further modified in view of Gordon, the resulting system would not include an implantable gastric stimulator that is configured to switch between any of a plurality of stimulation vectors depending upon sensed intrinsic gastric activity, per independent claim 1.

For at least these reasons, the Examiner failed to establish a *prima facie* case for non-patentability of independent claim 1 under 35 U.S.C. § 103(a) over Cigaina in view of Douglas and Gordon.

Independent claims 29, 35, and 36 include limitations similar to those of independent claim 1. For example, independent claim 29 recites the feature of selecting at least one of a plurality of stimulation vectors across the stomach wall for application of electrical stimulation based upon the sensed intrinsic gastric activity. Independent claim 36 recites the feature of selecting at least one of a plurality of stimulation vectors across the stomach wall for application of electrical stimulation to the patient based upon the sensed intrinsic electrical gastric activity. Accordingly, claims 29, 35, and 36 are patentable under 35 U.S.C. § 103(a) over the cited art for at least the reasons provided with respect to independent claim 1.

Independent claim 36 additionally includes the feature of withholding application of electrical stimulation to the patient when intrinsic electrical gastric activity is classified as abnormal. In support of the rejection of claim 36, the Examiner stated:

Regarding claim 36, Cigaina in view of Douglas and Gordon discloses a system that senses and then disrupts normal activity, but it is silent as to if the gastric pacemaker withholds stimulation when abnormal activity is present. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Cigaina in view of Douglas in view of Gordon, with a stimulator that only stimulates when normal waves are present since it was known in the art that a system that disrupts normal activity is not needed when normal activity is not present and thus withholding stimulation during unnecessary times provides the predictable results of disrupting normal activity without unnecessarily delivering stimulation to the patient in order to further provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.¹⁹

¹⁹ Final Office Action dated October 4, 2010 at pp. 5-6, item 15.

Thus, the Examiner admitted that Cigaina in view of Douglas and Gordon fails to disclose withholding application of electrical stimulation to the patient when intrinsic electrical gastric activity is classified as abnormal, as required by claim 36. In an attempt to overcome this deficiency, the Examiner asserted that it would have been known in the art to include this feature. Namely, the Examiner asserted that “it was known in the art that a system that disrupts normal activity is not needed when normal activity is not present.”

The Examiner appears to be relying on alleged common knowledge in the art in order to support the conclusion that the feature of withholding application of electrical stimulation to the patient when intrinsic electrical gastric activity is classified as abnormal would have been an obvious modification to Cigaina in view of Douglas and Gordon. However, the Examiner failed to provide any documentary evidence to support the conclusion that “it was known in the art that a system that disrupts normal activity is not needed when normal activity is not present.”

Applicant traverses the assertion of common knowledge in the art. Official notice without supporting documentary evidence should only be taken where the facts asserted to be well-known are capable of instant and unquestionable demonstration as being well-known.²⁰ In the present case, Applicant submits that the official notice apparently taken by the Examiner is not capable of instant and unquestionable demonstration as being well-known. For example, neither Cigaina nor Douglas nor Gordon, nor any combination of Cigaina, Douglas, and Gordon, contemplates withholding application of electrical stimulation to the patient when intrinsic electrical gastric activity is classified as abnormal. Thus, it is unclear why one having ordinary skill in the art would have modified Cigaina in view of Douglas and Gordon in the manner proposed by the Examiner.

For at least these reasons, the Examiner failed to establish a *prima facie* case for non-patentability of Applicant’s independent claims 1, 29, 35, and 36. Claims 2–9, 11–18, 27, 28, 30, 31, and 34 depend from one of independent claims 1, 29, 35, and 36 and, for at least the reasons provided with respect to the independent claims, the Examiner failed to establish a *prima facie* case for non-patentability of dependent claims 2–9, 11–18, 27, 28, 30, 31, and 34.

²⁰ MPEP § 2144.03

Dependent Claims

For at least the reasons provided above with respect to the independent claims, dependent claims 2–9, 11–18, 27, 28, 30, 31, and 34 are patentable over the cited art. In addition, the dependent claims recite additional features that are neither disclosed nor suggested by the cited art.

For example, claim 11 requires that the stimulator temporarily reverts to a power conserve condition in the absence of a programmable threshold of normal electrical activity. As discussed in the Amendment filed on November 18, 2009, Cigaina in view of Douglas and Gordon fails to disclose or suggest the features of claim 11. Although Gordon describes using a programmable calendar 48 to provide increased stimulation at certain hours of the day and decreased stimulation at other hours of the day, Gordon apparently discloses that the specific times for providing decreased stimulation are preprogrammed times based on when gastric activity is estimated to be less than other times of the day.²¹ In contrast, claim 11 requires that the stimulator revert to a power conservation condition in the absence of a programmable threshold of normal activity, rather than preprogrammed time periods as described by Gordon.

As another example, claim 14 specifies that electrical stimulation is delivered across the sensed intrinsic gastric activity. Claim 15 specifies that electrical stimulation is delivered with a spatial offset to the sensed intrinsic gastric activity. Claim 16 specifies that electrical stimulation is delivered with a temporal offset to the sensed intrinsic gastric activity and claim 18 specifies that the temporal offset is programmable by a user. Claim 17 specifies that electrical stimulation is delivered in anticipation of a next normal electrical activity. The applied references fail to disclose or suggest the features of dependent claims 14–18. As discussed in the Amendment filed on November 18, 2009, Applicant believes that the Examiner is misinterpreting the claims. In rejecting claims 14–18, the Examiner suggested that Douglas discloses that the stimulation is offset or direct, and that it would be preferable to stimulate the stomach “directly or indirectly” to provide increased disruption of the normal waves.²² However, claims 14–18 do not require “direct” or “indirect” stimulation. Douglas fails to disclose or suggest the features of claims 14–18. Although Douglas discloses that the frequency and voltage of stimulation pulses may be controlled, Douglas fails to contemplate stimulation that is delivered with a temporal offset to the

²¹ See Gordon, col. 10, l. 44 – col. 11, l. 41.

²² Final Office Action dated October 4, 2010 at p. 6, item 16.

sensed intrinsic gastric activity, in the example of claim 16. For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 14–18.

As another example, claim 30 specifies that the method of claim 29 further includes maintaining a history of predecessor electrical events. In support of the rejection of claim 30, the Examiner asserted that “Gordon teaches a device that contains memory for storing the stimulation data so that it can be reviewed later to help provide better stimulation.”²³ Applicant respectfully disagrees that the Gordon disclosure amounts to a disclosure of a method that includes maintaining a history of predecessor electrical events. Although Gordon describes a device including a memory provided to store data,²⁴ Gordon fails to contemplate maintaining a history of predecessor events, much less maintaining a history of predecessor electrical events.

For at least these reasons, the Examiner failed to establish a *prima facie* case for non-patentability of Applicant’s claims 1–9, 11–18, 27–31, and 34–36 under 35 U.S.C. § 103(a). Reconsideration and withdrawal of the rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. In view of the clear distinctions identified above between the current claims and the applied art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit to or acquiesce in any of the rejections or the Examiner’s interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

²³ *Id.* at p. 6, item 17.

²⁴ Gordon, column 5, lines 1-3.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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December 6, 2010

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